ATTACHMENT 'A' 1/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.:	10/064,566	:	Confirmation No.: 3231
Applicant:	Priya Gopinath et al.	:	Group Art Unit: 2621
Filed:	July 26, 2002	:	Examiner: Lavin, Christopher L.
Docket No.:	124320 / GEM-0041	:	

For: METHOD, SYSTEM AND COMPUTER PRODUCT FOR CALCULATING MASS SCORES

July 11, 2007

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.131

Kishore Acharya declares and states that:

1. I am an inventor of the subject matter of the rejected claims in the above-identified patent application.

2. I conceived in the United States subject matter disclosed and claimed in the above-identified patent application prior to March 29, 2002, and then diligently reduced the invention to practice in the United States before March 29, 2002.

3. As evidence in support of this prior conception and reduction to practice, submitted herewith is the following evidence of activity done in the United States, with dates and proprietary material redacted:

(a) Exhibit A is a copy of my invention disclosure form (IDF) created prior to March 29, 2002. The IDF contains 6 pages.

(i) The IDF states at the top of page 1 "Date Received: [redacted date prior to March 29, 2002]".

(ii) The IDF states under "Advantages of the Invention" on page 3 of the IDF, "The invention serves to address the need of an accurate mass score ..."

(iii) The IDF describes the claimed invention under the section titled "Invention Description" on pages 1-2. Excerpts of this section include: "The calibration process involves determining the CT HU for each of the calcium

ATTACHMENT 'A' 2/2

inserts and creating a curve with known densities of the inserts"; "The curve can then be used as a standard curve, which could be used in the conversion of patient CT HU units into patient calcium plaque density. The novelty of the invention is the use of a ... phantom in developing a 'single calibration curve set', which can then be used universally for the conversion computation."

(b) Exhibit B is a copy of an e-mail (with attachments) generated prior to March 29, 2002. The e-mail states that the attachments are plots of patient cases scored with SmartScore (a software program used to correlate mass scores to other calcium scores such as AJ, volume, and linear). The e-mail attachments depict interim test results of using different scoring methods (including a mass score or density score) on the same patient in two consecutive scans. Thus, the e-mail attachments show an actual reduction to practice of the claimed invention.

(c) Exhibit C is a copy an e-mail (with attachments) generated prior to March 29, 2002. The e-mail states that an initial comparison of a plaque score calculation for a single patient using five different scoring methods has been performed. Attached to the e-mail are two files showing a comparison between five different scoring methods (AJ130, AJ90, Linear, Volume and Mass). The e-mail shows interim test results of using a mass score (or density) for calcium scoring and an actual reduction to practice of the claimed invention.

4. The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Date: July 16, 2007.

Kishore C Acharya

Kishore Acharya

GE Medical Systems
Invention Disclosure Form

3000 North Grandview Blvd., W-710
P.O. Box 414, Waukesha WI 53188
(262) 544-3028; Dialcom: 8*320-3028

Docket No.: 124320

Mail to: PATENT OPERATION, W-710

Date Received: [redacted]

- **Use as many pages in this word document as necessary.**
- **You may attach additional materials to support this disclosure, for example, Tech Notes and Drawings. Such submitted materials must be referenced in this disclosure form. Each page of these materials must be dated, signed and witnessed in the same manner as this invention disclosure.**

MODALITY: *(e.g., CT, MR, Ultrasound, X-Ray)*

CT

INVENTION TITLE: *Provide a unique, descriptive title. If you write this disclosure in a language other than English, please provide a title in English as well. Si vous rédigez en français, merci de proposer un titre en anglais et un titre en français.*

A novel calibration technique for calculating mass scores.

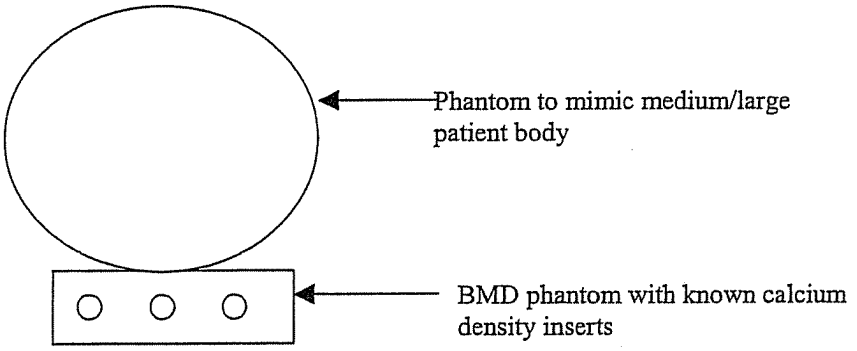
PROBLEM/BACKGROUND: *Describe the problem that is solved by the invention. Assume that the reader has a basic knowledge of your diagnostic imaging modality and related technologies.*

Mass scores of calcium in the coronary vessels require the use of density of the calcium plaque. This value is indirectly known through the CT Hounsfield of the calcium plaque. However, in order to convert CT hounsfield units into density values, a prior curve with known relationship between known calcium densities and corresponding CT HU values needs to be computed. Beam hardening is the attenuation of Xrays through the human body until the organ of interest comes in the path of the X-ray beam. It is thus necessary to incorporate the effect of beam hardening in the computation of the calibration curve. If the calibration process does not account for beam hardening, then an inaccuracy would be introduced in the calculation of the density and thus the mass score. The present invention relates to the development of a calibration process which accounts for beam hardening.

INVENTION DESCRIPTION: *Describe how the invention works and how it solves the problem posed above.*

The calibration process includes the use of a BMD phantom with three calcium inserts of known densities and a 35 and 48 cm poly phantom above it mimicking a medium to large patient. The apparatus is shown as in figure 1.

Figure 1



INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Priya Gopinath		X		
Kishore Acharya		X		
Jianying Li		X		

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE
Sean Lucas		
Darin Okerlund		

[redacted]

The poly phantom mimics the body of the patient in attenuating Xrays through it before the calcium inserts are intercepted in the path of the X-ray beam. The calcium inserts are of fixed densities of 50, 100 and 200 mg/cc. The background of the BMD phantom is also of a known fixed density. The calibration process involves determining the CT HU for each of the calcium inserts and creating a curve with the known densities of the inserts as shown below in figure 2.

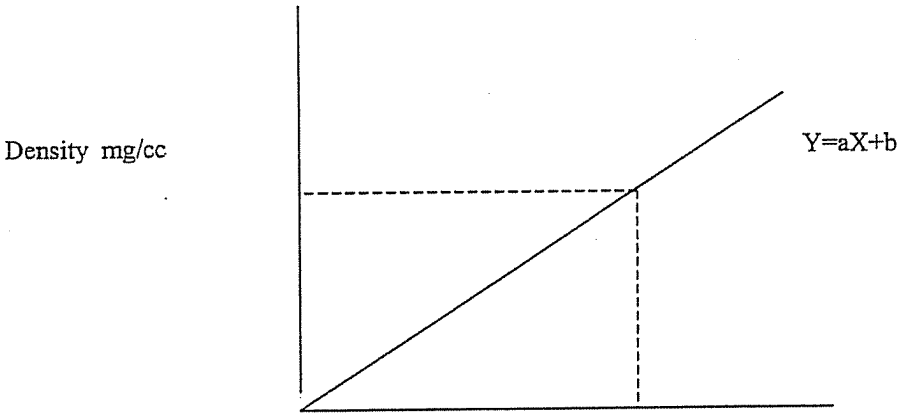


Fig 2

This curve can then be used as a standard curve, which could be used in the conversion of patient CT HU units into patient calcium plaque density. The novelty of the invention is the use of a poly phantom over the BMD phantom in developing a 'single calibration curve set', which can then be used universally for the conversion computation.

To improve the accuracy of the calibration process for different patient sizes, it is proposed to use a 35 and a 48 cm poly phantom, to mimic medium and large patient sizes. A calibration curve set can be developed to incorporate the variations due to different scan parameters, CT number drifts due to aging of the system, etc. Thus the proposed calibration process will set a range within which the above CT HU variations can be tolerated and a mechanism can be set up to alert the technologist if the CT hounsfield units step outside the bounds.

Many current calibration processes for other CT based applications requiring a similar computation use a 'on the fly' calibration technique. One advantage of our proposed technique for calcium scoring over it is that while the other calibration technique adapts to the variations listed above in a real time fashion, it does not contain any mechanism where the CT variations are constantly monitored to comply over the acceptable range. Thus it is inefficient in testing the accuracy of the conversion due to the system as a whole in spite of real time calibration.

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	**GE**	**NOT GE**	**DATE**
* Priya Gopinath		X		
Kishore Acharya		X		
Jianying Li		X		

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	**DATE**
Sean Lucas		
Darin Okerlund		

ADVANTAGES OF THE INVENTION: *Describe the benefits of the invention, both in technical terms (e.g., stronger, new application, faster imaging, etc.) and business terms (e.g., cost savings, product efficiency, etc.).*

The invention serves to improve the naure of mass score measurements in delivering a mass score in terms of density (mg/cc) as against the current score derived in terms of CT hounsfield units. The invention serves to address the need of an accurate mass score by GE software in a multi center study which aims at assessing the difference in scores between GE, Siemens, Toshiba, Philips scanners. The study is being conducted by a consortium of important researchers where GEMS needs to maintain its technology leadership status. It has a great impact on reducing complexity in design and logistics in providing an optimal solution after research as against providing a solution, which can handle variation but not accuracy. Accuracy and consistency is the goal. It helps in maintaining clinical productivity in producing quick results due to inbuilt calibration curves within the software. It prevents errors in score results due to operator error in the field.

CLAIM OF NOVELTY: *Describe what is novel, unique, non-obvious about this invention compared to previous designs or solutions identified in the Problem/Background or Prior Art sections. "Obvious" is defined with respect to an individual with an average working knowledge of the general area. Be careful: what is obvious to you, as a specialist, may not be obvious to someone with an average working knowledge. You should err on the side of assuming that your invention is non-obvious.*

See section on Invention description for information for this section.

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Priya Gopinath		X		
Kishore Acharya		X		
Jianying Li		X		

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE
Sean Lucas		
Darin Okerlund		

EXHIBIT A 4/6

Docket No. _____

SUMMARY QUESTIONS FOR INVENTION DISCLOSURE

(The answers to these questions will help the modality PEB with the patent filing decisions they make.)

1) **DESCRIBE ANY RECENT WORK ON DEVELOPING AND DEMONSTRATING THE IDEA AT GEMS.** *Has feasibility been proven? How? Is there a prototype?*

A DOE has been set up to develop the work in the development of the calibration process to generate the curves. Preliminary feasibility studies are underway.

2) **ARE THERE ANY PLANS TO USE THE INVENTION IN A PRODUCT?** *Give Product/Program name and milestone dates if known. Has this invention been identified as a program deliverable?*

Yes, the curves generated will be used in the [redacted]. This invention has been identified as a deliverable.

3) **WHAT ARE THE PLANS OR DESIRES TO PUBLISH?** *It is absolutely critical to identify the earliest possible public disclosure of the invention for legal reasons. This may include publication, installation of prototype, trade shows, etc. GEMS can lose the right to patent an invention by premature public disclosure.*

4) **DESCRIBE ANY KNOWN RELEVANT COMPETITOR ACTIVITY.** *Are any competitors working on solutions to the same problem? Have any competitors addressed the same problem?*

[redacted]

5) **WAS THIS INVENTION DEVELOPED IN THE COURSE OF A PROJECT WHICH WAS FUNDED IN PART BY AN ENTITY OTHER THAN GE?** *Has any work been done, for example, with Government funding, university collaboration, even if such funding was provided indirectly, as via CRD?*

[redacted]

6) **WHAT IS THE EARLIEST TANGIBLE DOCUMENTATION OF THIS INVENTION?** *Is it a lab notebook, engineering report, etc., or this disclosure document? If not this document, please provide a reference and a date.*

[redacted]

7) **HOW MUCH DIFFICULTY WOULD A COMPETITOR EXPERIENCE IN TRYING TO DESIGN AROUND THIS INVENTION?** *Are there many ways of relatively equal difficulty to solve the problem, or is the invention a unique solution in terms of benefit and simplicity?*

[redacted]

[redacted]

EXHIBIT A 5/6

DISCLOSURE QUALITY TRACKER

This sheet is a process improvement tool used only to verify that the disclosure process meets customers' CTQ's.

☐ All Inventor Signatures ☐ 2 Witness Signatures ☐ Any Prior Art Supporting Materials Attached ☐ Datasheet Completed for All Inventors ☐ Complete Checklist above and Submit Original Disclosure and Supporting Materials to Patent Operation (W-710)	**INVENTOR CHECKLIST**
☐ Docket No. _____ ☐ Inventor Notified of Receipt and Docket No.	**PATENT OPERATION**

Score each section by circling appropriate number: (1 = below expectation; 3 = meets expectation; 5 = exceeds expectation)

1 - 3 - 5 Invention Title 1 - 3 - 5 Problem/Background 1 - 3 - 5 Invention Description 1 - 3 - 5 Drawing 1 - 3 - 5 Advantages of the Invention 1 - 3 - 5 Prior Art 1 - 3 - 5 Claim of Novelty 1 - 3 - 5 Completed Summary Questions	**PATENT EVALUATION BOARD RATING** **TOTAL: _____**
☐ File ☐ Hold (C_____) Date:_____ ☐ Inactivate ☐ Trade Secret ☐ Publish ☐ Foreign Filing: (Yes ☐ No ☐)	**PEB DECISION**
Meeting Date / Date Advised of Status _____ _____ _____ _____	**PEB NOTIFICATION OF DECISION TO INVENTOR**

Score each section by circling appropriate number: (1 = below expectation; 3 = meets expectation; 5 = exceeds expectation)

1 - 3 - 5 Inventor Responsiveness 1 - 3 - 5 Relevance of Prior Art 1 - 3 - 5 Overall Quality of Disclosure	**OUTSIDE COUNSEL RATING** *(to be completed and returned to GEMS Patent Operation along with patent application papers)*

EXHIBIT B 1/6

[redacted]

From: Christopher Woodhouse [cwood@welchlink.welch.jhu.edu]
Sent: [redacted]
To: WarrenJ969@aol.com; Fox, Stanley H (MED); Theophano.Mitsa@med.ge.com; Jeffrey Carr; Dr. Arthur Agatston; Acharya, Kishore C (GE Healthcare); YANADA, TORU (MED,CT JP)
Subject: SmartScore: to-date results of reproducibility study, 1second scanner

[redacted]
Miami Beach, FL

Dear Colleagues,
Attached please find log-log plots of 17 cases scored to-date with SmartScore. All of the data is from 1000 msec rotation scanner gantries on both a HiSpeed Advantage (RP) and CT/i scanners.
I think the data compares favorably with EBCT, so far.
Regards,
Chris

Chris Woodhouse, MD, MSEE
Staff Radiologist, Baptist Health Systems of Florida
Research Associate, Mount Sinai Hospital of Miami Beach,
1324 Euclid Avenue, Suite 6, Miami Beach, FL 33139
305/674-2680 Day, 305/535-6574 Night, 305/291-0666 pager
home page: http://smithhamilton.com/cew
It is Hard to say what is Impossible, for the Dream of Yesterday


LogAJ.jpg


LogAJ90.jpg

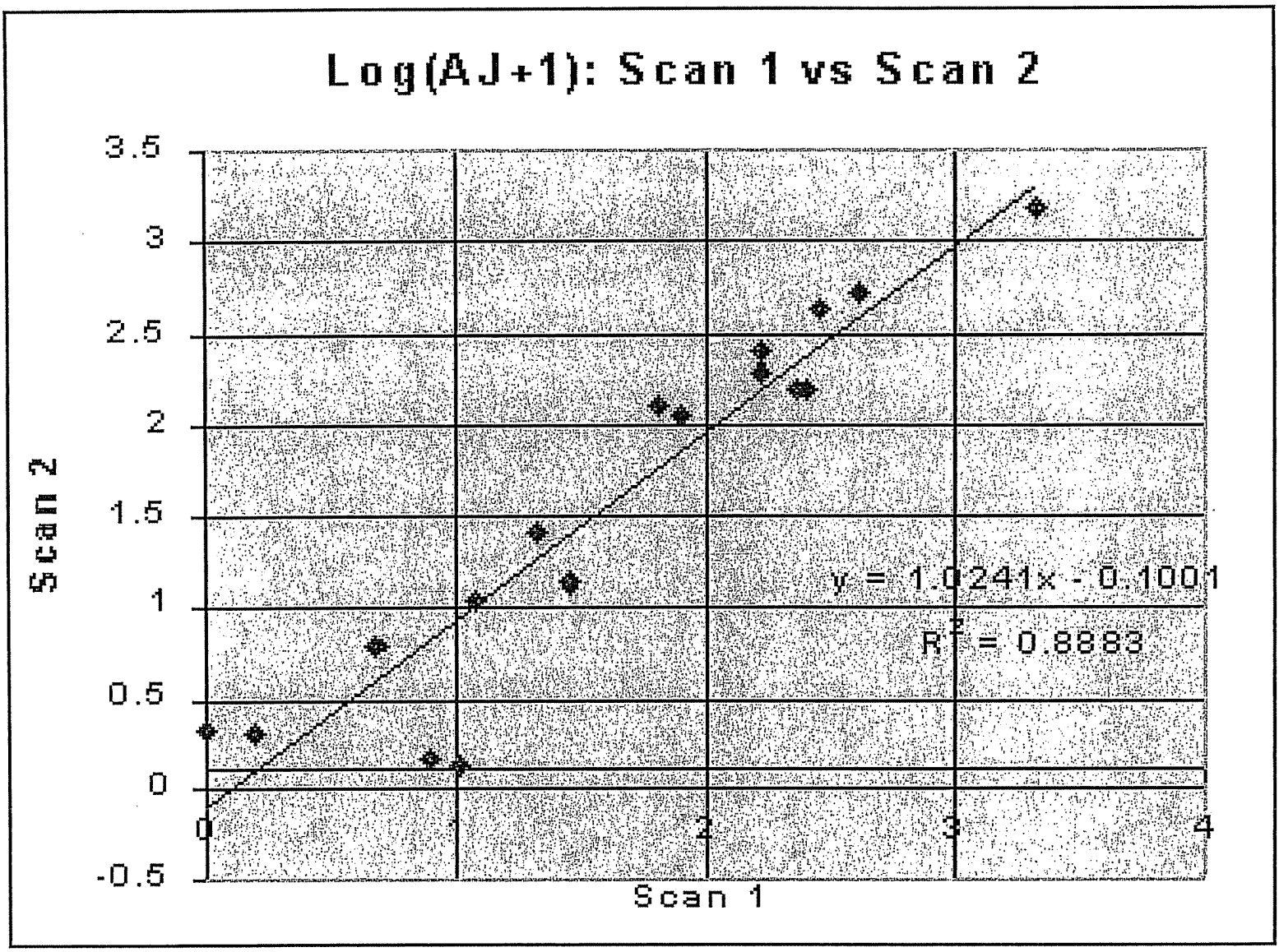

Volume.jpg

Is the Hope of Today, and the Reality of Tomorrow. Robert Goddard


Mass.jpg


Linear.jpg

EXHIBIT B 2/6


Log(AJ+1): Scan 1 vs Scan 2
Scan 2
Scan 1
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0
1
2
3
4
y = 1.0241x - 0.1001
R² = 0.8883

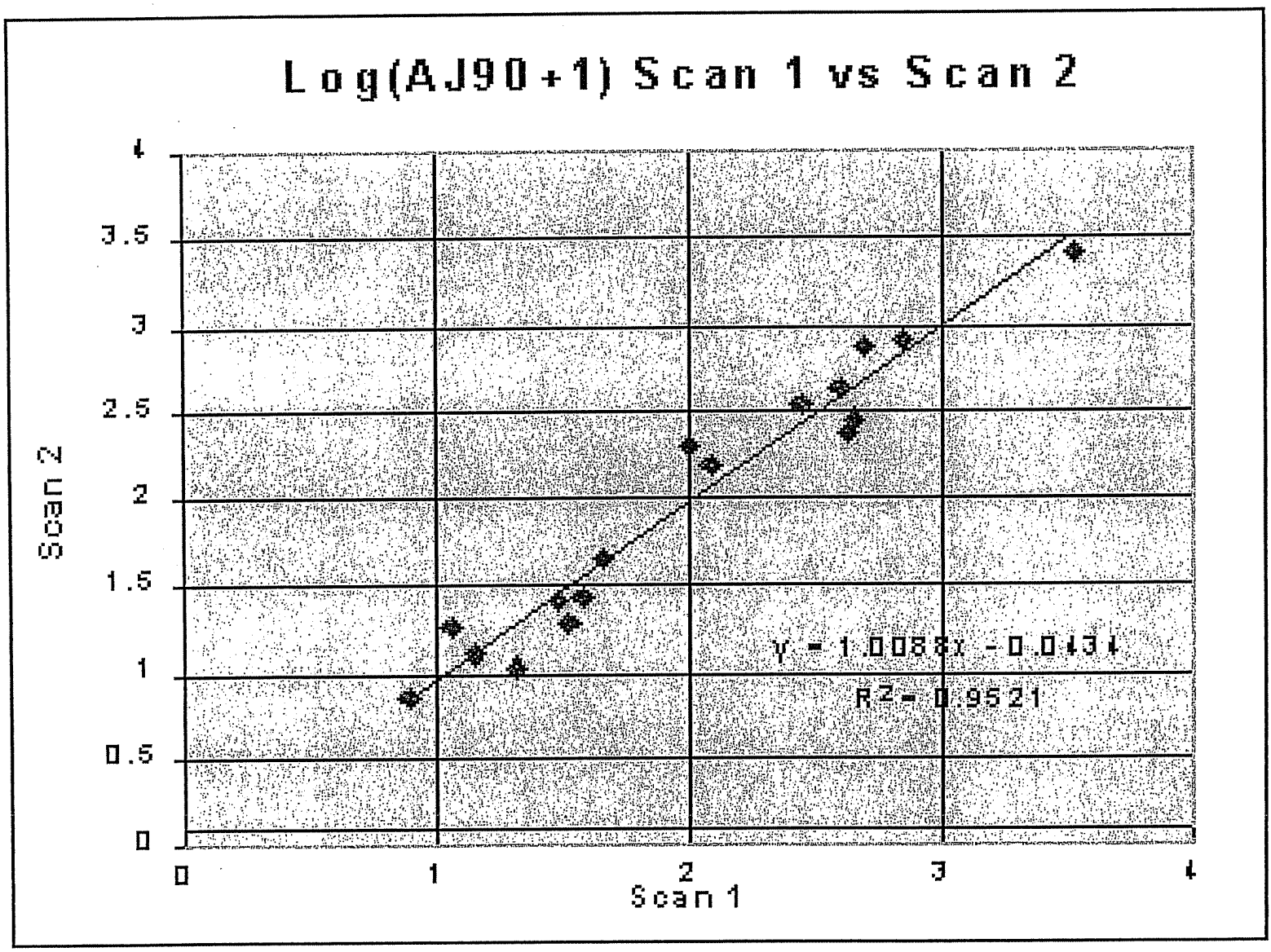

Log(AJ90+1) Scan 1 vs Scan 2
Scan 2
Scan 1
0
0.5
1
1.5
2
2.5
3
3.5
4
y = 1.0088x - 0.0431
R2 = 0.9521

EXHIBIT B 4/6

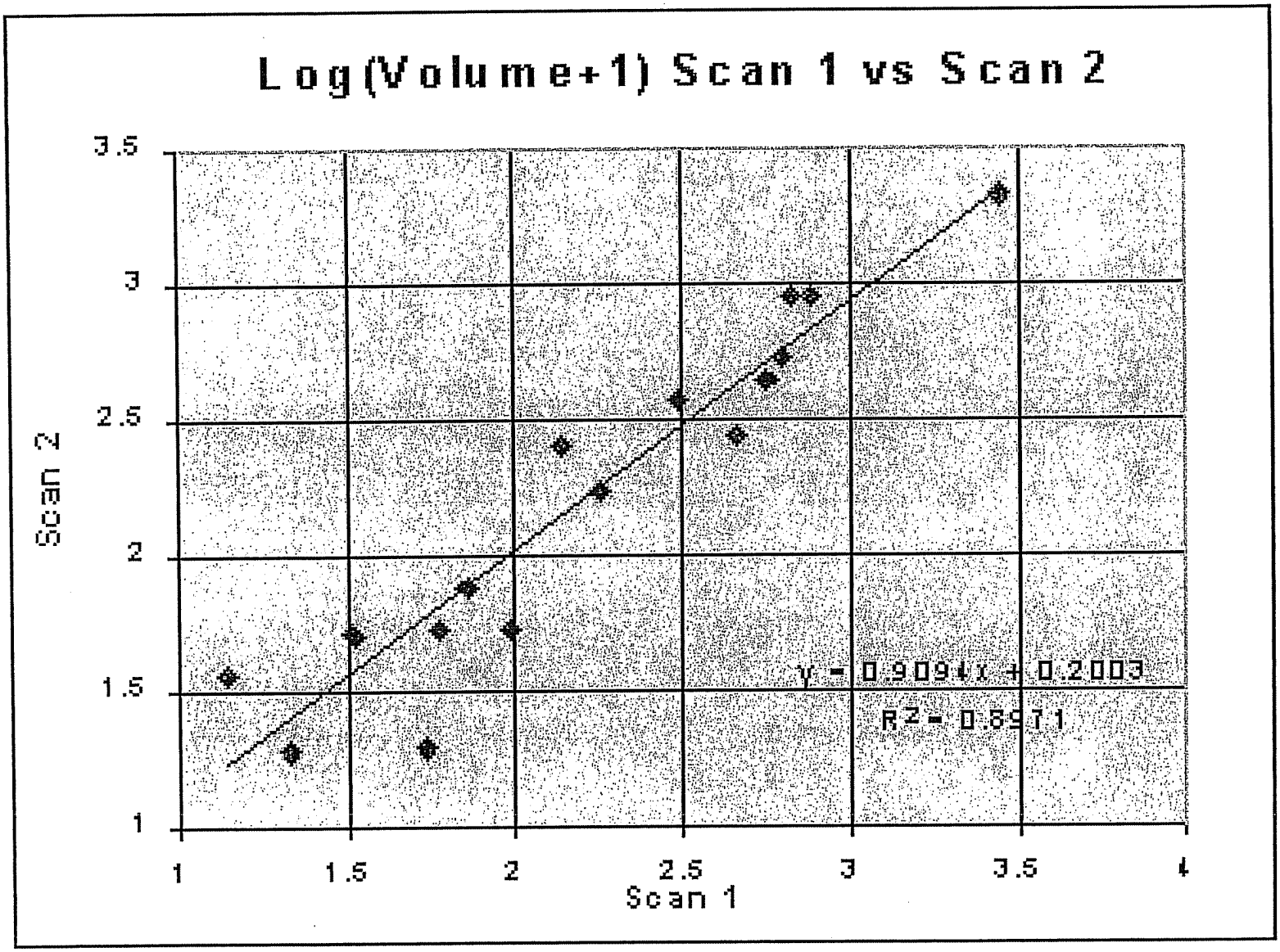

Log(Volume+1) Scan 1 vs Scan 2
Scan 2
Scan 1
3.5
3
2.5
2
1.5
1
1
1.5
2
2.5
3
3.5
4
y = 0.909x + 0.2003
R² = 0.8971

EXHIBIT B 5/6

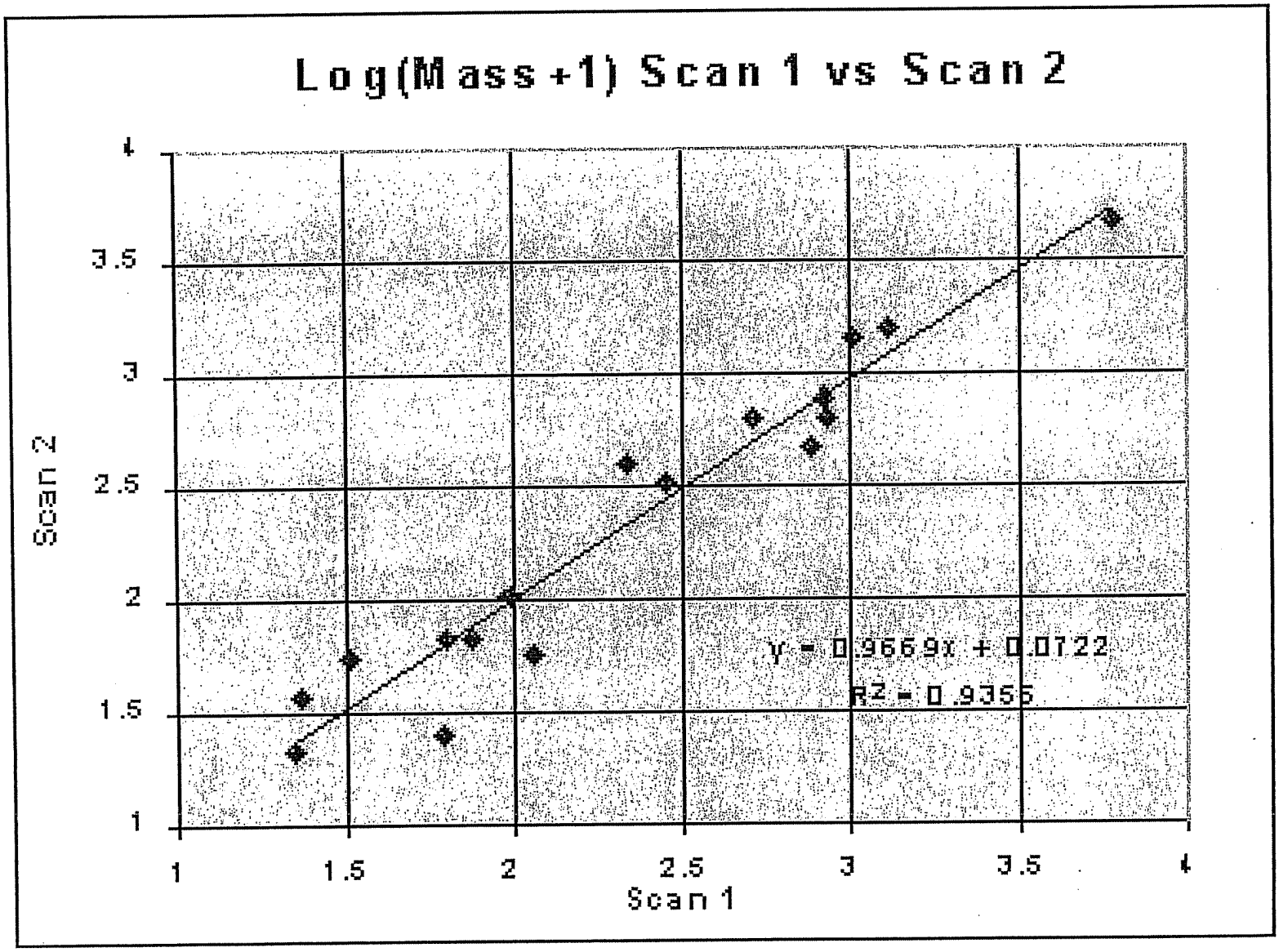

Log(Mass+1) Scan 1 vs Scan 2
Scan 2
Scan 1
1
1.5
2
2.5
3
3.5
4
y = 0.9669x + 0.0722
R² = 0.9356

EXHIBIT B 6/6

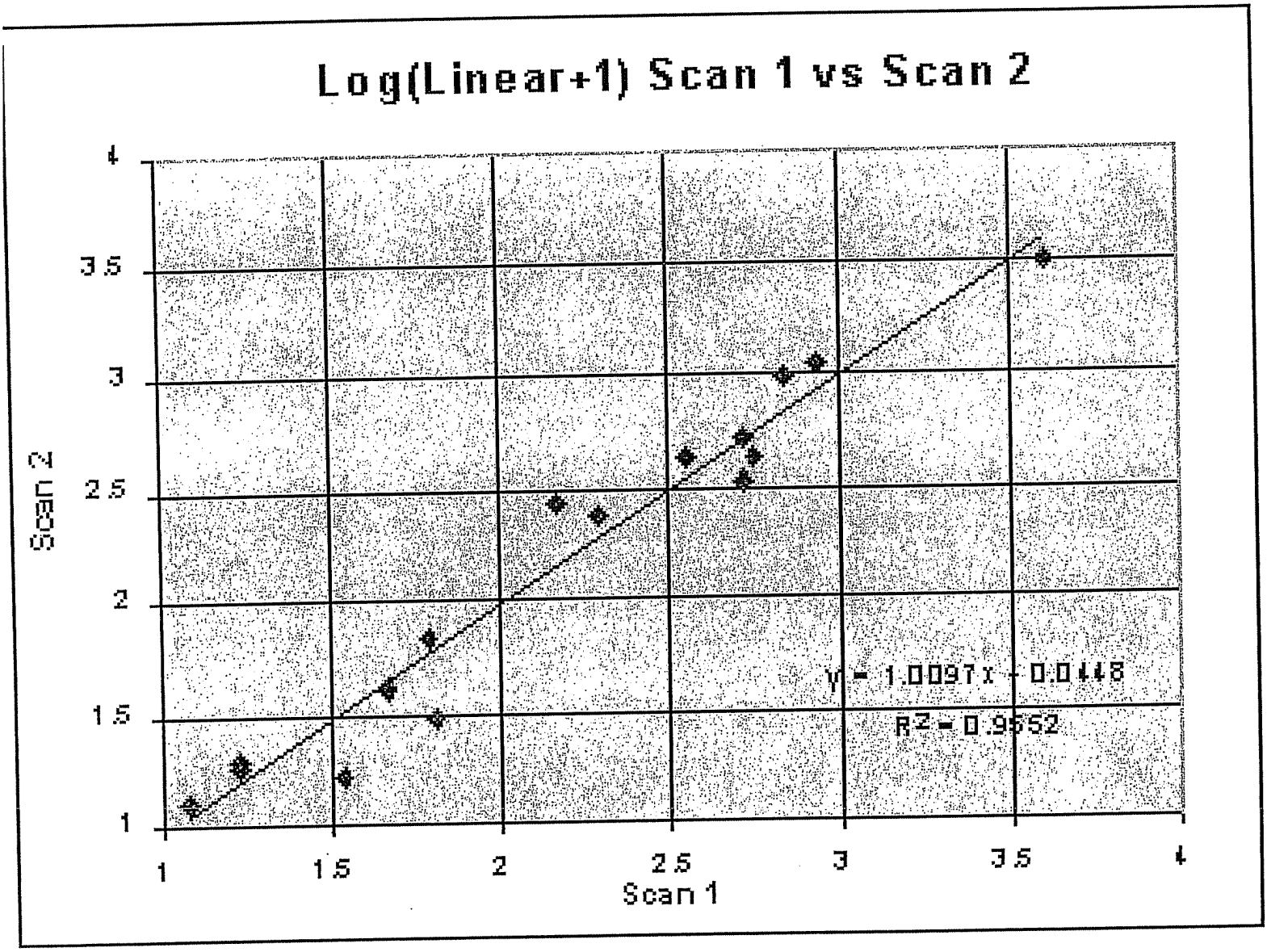

Log(Linear+1) Scan 1 vs Scan 2
Scan 2
Scan 1
y = 1.0097x - 0.0448
R2 = 0.9552
1
1.5
2
2.5
3
3.5
4

EXHIBIT C 1/5

[redacted]

From: J. Jeffrey Carr, MD, MS [jcarr@rad.wfubmc.edu]
Sent: [redacted]
To: jcarr@wfubmc.edu
Cc: Kishore C Acharya; Robert Buchanan; He, David; Beckett, Bob L (MED); Monke, Travis R
Subject: Re: Scoring algorithm Research release SmartScore[redacted]

attached are the reports - Please also send instruction on how to
reactivate the logfile logging with the new version. SmartScore in no
longer creating logfiles - is this valuable option still avialable?
"J. Jeffrey Carr, MD, MS" wrote:
>
> My lab has performed initial comparision of the plaque score calculation
> between SmartScore versions [redacted] and [redacted] Methods: we compared plaque
> score on the same images on the two software versions. Overall the
> calculated scores were identical except for two slices where the
> calculated score was slightly different:
>
> score version 1.1 2.0.1
> image 21 159 157 method = volume
> image 22 105 106 method = volume
>
> I reselected the roi several ways with the region grow and box. I do not
> believe the difference is secondary to my roi selection technique. Is
> there a very slight difference between the score calculation algorithms
> in any of the following:
> rounding
> threshold
> filter
> scorerclass (i.e. stepper / volume algorithm)
>
> I do not believe that this small difference is clinically significant.
>
> PS I also noticed that the "Analysis" / "Images" display of slice time
> and location may have a bug in it. I ran this study on my carotid (neck)
> ct's to eliminate motion artifacts and to get bigger plaques which are
> more reproducible (although it really shouldn't matter if you use the
> exact same images). I noticed that despite each slice of the helical
> acquistion being at a different location it grouped 3 of the images as
> being in the same set and would allow selection of only 1 image per set
> - I was able to correct this by going to the "select" menu and
> un-checking the max images for set box. This also does not represent a
> major problem but is FYI.
>
> Hope this feedback is helpful. I really like the new program and the
> sscore config application. I need some documentation especially on the
> scoring algorithms
>
> jeff
>
> ---
> Name: jcarr.vcf
> jcarr.vcf Type: VCard (text/x-vcard)
> Encoding: 7bit


sscore_369473_95 3731306976.txt...


sscore_369473_95 3665725627.txt...


Card for J. Jeffrey Carr, MD, ...

> Description: Card for J. Jeffrey Carr, MD, MS

EXHIBIT C 215

sscore_369473_953731306976.txt

SmartScore 369473 [redacted] 8:21:46 AM
N.C. BAPTIST HOSPITAL
EKG:null null null
Heart Rate:0

Patient ID:369473
Name:DHS3401SHELWA
Age:
Sex:
Ethnicity:
Weight:
Height:
Cholesterol:
LDL:
HDL:
Triglycerides:
Diabetes:N
Smoking:N
Packs:
Years:
Medications/
/Medications
Cardiac History/
/Cardiac History
Previous Calcification Scores/
/Previous Calcification Scores
Family Cardiac History/
/Family Cardiac History
Study Notes/TEST COMPARING TO NEW SMARTSCORE 2.1.0 (RESEARCH)
/Study Notes

	LMA	LAD	LCX	RCA	PDA	A	B	C	Total
AJ 130	0	0	0	0	51	837	12	0	900
AJ 90	0	0	0	0	80	1,044	24	0	1,147
Linear	0	0	0	0	91	1,700	31	0	1,821
Volume	0	0	0	0	64	783	36	0	882
Mass	0	0	0	0	127	2,930	49	0	3,105

AJ 130
image:16 B:4/12 total:4/12
image:17 A:46/139 total:46/139
image:18 A:75/224 total:75/224
image:19 A:79/237 total:79/237
image:20 A:47/140 total:47/140
image:21 A:32/97 total:32/97
image:22 PDA:17/51 total:17/51
totals: LMA:0 LAD:0 LCX:0 RCA:0 PDA:51 A:837 B:12 C:0
grand total:900

AJ 90
image:16 B:8/24 total:8/24
image:17 A:56/168 total:56/168
image:18 A:83/249 total:83/249
image:19 A:91/274 total:91/274
image:20 A:71/213 total:71/213
image:21 A:47/140 total:47/140
image:22 PDA:26/78 total:26/78
image:23 PDA:0/2 total:0/2
totals: LMA:0 LAD:0 LCX:0 RCA:0 PDA:80 A:1,044 B:24 C:0
grand total:1,147

Linear
image:16 B:10/31 total:10/31

image:17 A:96/287 total:96/287
image:18 A:166/499 total:166/499
image:19 A:168/504 total:168/504
image:20 A:87/262 total:87/262
image:21 A:49/148 total:49/148
image:22 PDA:29/88 total:29/88
image:23 PDA:0/3 total:0/3
totals: LMA:0 LAD:0 LCX:0 RCA:0 PDA:91 A:1,700 B:31 C:0
grand total:1,821

Volume
image:16 B:12/36 total:12/36
image:17 A:42/126 total:42/126
image:18 A:62/187 total:62/187
image:19 A:68/205 total:68/205
image:20 A:53/159 total:53/159
image:21 A:35/105 total:35/105
image:22 PDA:20/59 total:20/59
image:23 PDA:2/5 total:2/5
totals: LMA:0 LAD:0 LCX:0 RCA:0 PDA:64 A:783 B:36 C:0
grand total:882

Mass
image:16 B:16/49 total:16/49
image:17 A:173/520 total:173/520
image:18 A:326/979 total:326/979
image:19 A:274/823 total:274/823
image:20 A:134/403 total:134/403
image:21 A:68/205 total:68/205
image:22 PDA:40/121 total:40/121
image:23 PDA:2/5 total:2/5
totals: LMA:0 LAD:0 LCX:0 RCA:0 PDA:127 A:2,930 B:49 C:0
grand total:3,105

EXHIBIT C 4/5

sscore_369473_953665725627.txt
SmartScore 369473 [redacted] 2:08:45 PM
N.C. BAPTIST HOSPITAL
EKG:none

Patient ID:369473
Name:DHS3401SHELWA
Age:
Sex:
Ethnicity:
Weight:mhs
Height:carotid
Cholesterol:
LDL:1
HDL:1
Triglycerides:right
Diabetes:N
Smoking:N
Packs:
Years:
Medications:
Cardiac History:
Previous Calcification Scores:
Family Cardiac History:
Study Notes:
practice with new software

Scored By:msp

	LMA	LAD	LCX	RCA	PDA	A	B	C	Total
AJ130	0	0	0	0	51	836	12	0	899
AJ90	0	0	0	0	80	1,042	24	0	1,146
Linear	0	0	0	0	91	1,699	31	0	1,821
Mass	0	0	0	0	126	2,927	49	0	3,102
Volume	0	0	0	0	64	781	36	0	881

EXHIBIT C 6/5

[redacted]

Full Name: J. Jeffrey Carr, MD, MS
Last Name: Carr
First Name: J. Jeffrey

Business: [redacted]
Business Fax: [redacted]

E-mail: jcarr@wfubmc.edu